510(k) NOTIFICATION SIEMENS SC7000 and SC9000XL INFINITY Modular BedsideMonitors

510(k) SUMMARY as required per 807.92(c)

Submitters Name, Address:

Siemens Medical Systems, Inc. Electromedical Systems Group, PCS

Danvers, MA 01923 Tel: (978) 907-7500 Fax: (978) 750-6879

Official Correspondent: David Simard, Director

Quality Assurance & Regulatory Affairs

Contact person for this submission: Jacqueline Emery Date submission was prepared: February 27, 1998

Trade Name, Common Name and Classification Name:

A. Trade Name:

Siemens SC7000 & SC9000 XL INFINITY Modular Bedside Monitor Series

B. Common Name, Classification Name, Class and Regulation Number:

Common Name	Classification	Class	Regulation Number
Common Name	Number		
	74DRT	II	21 CFR 870.2300
Cardiac monitor	74BWS	II	21 CFR 870.2300
Pulse rate monitor	74DQA	TT	21 CFR 870.2700
Pulse oximeter	73BZQ	II	21 CFR 868.2375
Breathing Frequency Monitor	80BWX	11	21 CFR 880.2910
Clinical Electronic Thermometer		<u> </u>	21 CFR 870.1110
Indwelling Blood Pressure Monitor	74CAA	11	21 CFR 870.2300
Heart Rate Monitor, Neonatal	74FLO		21 CFR 868.2375
Ventilatory Effort Monitor (Apnea Detector)	73FLS	II	21 CFR 870.1110
Monitor Blood Pressure, Neonatal, Invasive	74FLP	II	
Arrhythmia detector & Alarm	74DSI	III	21 CFR 870.1025
Medical Cathode-Ray Tube Display	74DXJ	II	21 CFR 870.2450
Medical Cathode-Ray Tube Display	74MLD	III	21 CFR 870.1025
ST Segment Monitor with Alarm	74DXN	II	21 CFR 870.1130
Non-indwelling Blood Pressure Monitor	73CCK	111	21 CFR 868.1400
End-tidal Carbon-Dioxide Monitor		1	

Predicate Device Identification:

Siemens SC9000/SC9015 Patient Monitoring System, original 510(k) submission K946306.

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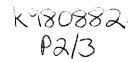
COMPANY CONFIDENTIAL

Siemens Medical Systems, Inc.

16 Electronics Avenue Danvers, MA 01923 USA

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Telex: 511958 (Siemensm SD)



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Device Description:

The SC 7000 and SC 9000XL modular bedside monitors are enhanced versions of the SC 9000 (predicate device - original submission K946306) and use the same front panel display and user interface as the SC 9000. In addition, the SC 9000 docking station is compatible with the SC 7000 and SC 9000XL for power and communication capabilities.

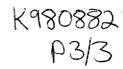
The SC 7000 (mid-level monitor) and the SC 9000XL (high-end monitor) are additions to the Siemens INFINITY Modular Portable Bedside Monitoring Series. Both the SC 7000 and SC 9000 XL utilize the same electronics and software, but with different base configurations and available options.

Intended Use:

The intended use of the SC 7000 and SC 9000XL Bedside Monitoring Series is to measure heart rate, respiration rate, invasive pressure, non-invasive pressure, arrhythmia, temperature, arterial oxygen saturation and pulse rate, cardiac output, central apnea, and ST segment analysis. This device will produce visual and audible alarms if any of these parameters vary beyond preset limits and produce timed or alarm recordings. This device will connect to a Siemens R50 Bedside Recorder, either directly or via the Infinity network.

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Table of Device Similarities and differences to predicate device

	Substantial Equivalent Device	Applicant Siemens Medical Systems	
,	Siemens SC9000	Siemens SC 7000	Siemens SC9000 XL
	Siemens	Same	Same
Manufacturer	K946306 (original submission)	To be assigned	
510(k) Number	The intended use of this device	Same	Same
Intended Use	is to measure heart rate,	_	
	respiration rate, invasive		
	pressure, non-invasive pressure,		1
	arrhythmia, temperature, cardiac		1 .
	output, arterial oxygen		
	saturation, pulse rate, cardiac	•	
	output, end-tidal carbon dioxide,		
	(central) apnea, and ST Segment		
	Analysis. This device will		
	produce visual and aural alarms		
*	if any of these parameters vary		
	beyond preset limits and produce timed or alarm recordings. This		
	device will connect to a Siemens		
	R50 Bedside recorder, either		
	directly or via the Infinity		
	Network.		
Intended Population	Adult/Pediatric/Neonatal	Same	Same
Intended Environment	In a healthcare environment	Same	Same
Michaed Environment	where patient care is provided		
	by healthcare professionals.		
Display type	Color TFT, 10.4"	Same	Same
Waveforms	Up to 8	Same	Same
Arrhythmia Detection	Basic	Same	Same
	Enhanced Optional		
Modular	Yes	Same	Same
Networking	Standard	Same	Same
NBP	Oscillometric	Same	Same
MIB	Compatible	Same	Same
MultiGas	Compatible	Same	Same
ST	3/7/8 leads	Same	Same
IBP	Up to 8 channels	Same	Same

Assessment of non-clinical performance data for equivalence: See Section U

Assessment of clinical performance data for equivalence: See Section V

Biocompatability: Not applicable

Sterilization: Not applicable

Standards and Guidances: See Section W

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Food and Drug Administration 9200 Corporate Boulevard Rockville MD 20850

JUN 5 **1998**

Ms. Penelope H. Cameron Regulatory Submissions Manager Siemens Medical Systems, Inc. 16 Electronics Avenue Danvers, MA 01923

Re: K980882

Siemens SC 7000/SC 9000XL INFINITY Modular Bedside Monitors

Regulatory Class: III (three)

Product Code: DSI Dated: March 4, 1998 Received: March 9, 1998

Dear Ms. Cameron:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Thomas J. Callahan, Ph.D.

Director

Division of Cardiovascular, Respiratory, and Neurological Devices Office of Device Evaluation Center for Devices and Radiological Health

Thomas J. Cellelon

Enclosure

	Page I OI I
510(k) Number (if known):
Device Name:	Siemens SC 7000 and SC 9000 XL INFINITY Modular Bedside Monitors
Indications for U	se:
The SC 7000 and SI	C 9000XL INFINITY Modular Bedside monitors are capable of monitoring:
Heart rate	2 3000XF INT INTO CITIES SASSICE INSTITUTE OF THE PROPERTY OF
Respiration rate	3
Invasive pressu	
 Non-invasive p 	ressure
 Arrhythmia 	
 Temperature 	
 Cardiac output 	
Arterial oxyger	i saturation
Pulse rateEnd-tidal carbo	un dinvida
• (central) apnea	
 ST segment an 	·
01 006	
	No. 5
	as TM and MultiGas ^{+TM} modules the SC 7000 and SC 9000XL are capable of measuring:
Respiration rat	
•	cpired Carbon Dioxide (CO2) cpired Oxygen (MultiGas+TM only)
	ed Oxygen (MultiGas [™] only)
	cpired gas concentrations of Enflurane, Halothane, Isoflurane, Desflurane, Sevoflurane,
and Nitrous O	
The SC 7000 and S	C 9000XL can interface with third party devices.
Professionals, i.e. I	ended to be used in the environment where patient care is provided by Healthcare Physicians, Nurses, and Technicians, who will determine when use of the device is on their professional assessment of the patient's medical condition.
parameter Cardiac	ended to be used on Adult, Pediatric and Neonatal populations, with the exception of the Output and ST Segment Analysis which are intended for use in the adult and pediatric and Arrhythmia which is intended for use in the adult population only.
MRI Compatibilit The Siemens SC 76 in a MRI magnetic	000 and SC 9000XL INFINITY Modular Bedside Monitors are not compatible for use
(PLEASE DO N NEEDED)	NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF
	Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801	

(Division Sign-Off)
Division of Cardiovascular, Respiratory,

Division of Cardiovacana And Neurological Devices

(Optional Format 1-2-96)